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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,961	12/30/2002	Ying Luo	A-68297-1/RMS/DHR	4915
20350	7590	06/09/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			ANDRES, JANET L	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,961	LUO ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 13-16, 20, and 22-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-12, 17-19 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, polypeptides in the reply filed on 25 March 2004 is acknowledged. The traversal is on the ground(s) that the groups stem from a common concept and are thus related. This is not found persuasive because, as was stated in the previous office action, they are not related in structure or function and thus there is no linking technical feature.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-28 are pending in this application. Claims 1-9, 13-16, 20, and 22-28 are withdrawn from consideration as being drawn to a non-elected invention. Claims 10-12, 17-19, and 21 as it depends from claims 17-19, are under examination in this office action.

Specification

2. The use of the trademark GENECHIP has been noted on p. 43, lines 4 and 17, of this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Objections

3. Claim 21 objected to because of the following informalities: It depends in part from non-elected claim 20. Appropriate correction is required.

Claim Rejections - 35 USC § 101

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4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 10-12, 17-19, and 21 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" use for the claimed invention. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966):

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

The claims are drawn to a kinase, Mkinase. What is disclosed (pp. 52-53) is that this kinase phosphorylates myelin basic protein, a frequently used substrate, that is cytoplasmic, and that it may bind to many other proteins, including TRAF4, as indicated by two-hybrid screening. Applicant further teaches that the kinase is involved in the cell cycle and thus may be used to screen for compounds that affect the cell cycle (p. 30). However, Applicant has provided no teachings as to how the kinase affects cell division and thus how it could be used to identify modulators of the cell cycle. Applicant provides no teachings as to the effect of the interaction of Mkinase with TRAF4 or any other protein. There is no indication as to what effect TRAF4 or any of the other proteins identified by two-hybrid screening have on the activity of Mkinase, what physiologically relevant substrates Mkinase phosphorylates, or what the consequences of

any binding or phosphorylation might be. Thus there is “no specific benefit in currently available form” associated with these interactions. Similarly, there is no specific and substantial utility associated with screens for agents that bind to Mkinase or inhibit its binding to TRAF4, as claimed in claims 17-19 and 21, since one of skill would not know what activity would be expected to be modulated by a molecule so identified. There is no "real world" use associated with the identification of modulators of a protein whose significance itself is unknown. Thus, clearly, further research would be required to ascertain the role of Mkinase in the cell cycle, and thus how compounds that affect it would affect the cell cycle. See *Brenner v. Manson*, noting that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.” A patent is therefore not a license to experiment.

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification’s disclosure of the properties of a material. The instant specification teaches that the claimed protein has a kinase domain and phosphorylates the MAP kinase substrate myelin basic protein (p. 52). Absent evidence that it phosphorylates the same site as MAP kinases, this teaching is not sufficient to identify the protein as a MAP kinase. However, such identification would not provide the polypeptide and encoding polynucleotides with a well-established utility. MAP kinases are involved in signaling by many cell-surface receptors, and MAP kinases and CDKs have diverse functions (Cook et al., *Biochem. Soc. Trans.* 2000, vol 28, pages 233-240). MAP kinase-induced pathways can inactivate CDKs (Fig. 1, p. 234); further, the role of MAP kinase itself depends on the duration and magnitude of activation (p. 236). Thus, the disclosed

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homology to these kinase families does not endow Mkinase with a well-established utility; such kinases have diverse functions.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 10-12, 17-19, and 21 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. Claims 10, 11, 17-19, and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, were it enabling for the polypeptides of SEQ ID NO: 2, would still not be enabling for polypeptides of limited homology to SEQ ID NO: 2 that bind to TRAF4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are drawn to polypeptides having at least 95% homology to SEQ ID NO: 2 that bind to TRAF4 and methods of using them. Applicants have taught the polypeptide of SEQ ID NO: 2. However, the biological function, activity, or essential properties of this protein are not defined. Kinases, even MAP kinase-related kinases, have diverse functions, as stated above. Thus the statement that a polypeptide is believed to be a member of this family would provide no guidance as to its actual biological function or activity. Binding to TRAF4 does not serve to provide the claimed proteins with a biological function; there is no significance or activity associated with this binding. Thus, were one of skill in the art able to use the protein of SEQ ID NO: 2, one of skill would still be unable to use proteins having limited homology to SEQ ID NO: 2 and having only the common characteristic of TRAF4-binding activity. Since detailed information regarding the structural and functional requirements of SEQ ID NO: 2 are lacking, it is unpredictable as to which variations, if any, could be made and used by the skilled artisan. Therefore it would require undue experimentation by one of skill in the art to practice the invention as claimed without further guidance from the instant specification.

9. Claims 10, 11, 17-19, and 21 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are drawn to a genus, polypeptides of at least 95% identity to SEQ ID NO: 2 that bind TRAF4. Applicant has disclosed one species, the polypeptide of SEQ ID NO: 2, but has not disclosed sufficient species for the broad genus of polypeptides of 95% identity to SEQ ID NO: 2 that bind TRAF4. The instant specification fails to provide sufficient descriptive

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information, such as definitive structural or functional features of the claimed genus. There is no description of the conserved regions that are critical to the structure and function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from other kinases are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed: there is no guidance in the art as to what the defining characteristics of Mkinase might be. Binding to TRAF4 is not sufficient to identify a genus; since there is no particular function associated with this binding, it does not impart any common characteristics to the claimed genus, by which the artisan would be able to recognize other members of the genus. Thus, no identifying characteristics or properties of SEQ ID NO: 2 are provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, the disclosure of SEQ ID NO:2 is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

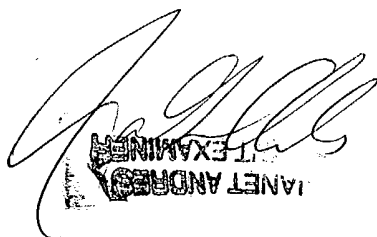
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.
Primary Examiner

8 June 2004

A handwritten signature in cursive script, likely of Janet L. Andres, is written over a rectangular stamp. The stamp contains the text "JANET ANDRES, PH.D." and "EXAMINER" in a bold, sans-serif font.